K132356

SciCan

JAN 31 2014

001_510k SUMMARY

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Date prepared
April 15th, 2013

Name of device

Trade Name:	SANAO
Classification Name:	Handpiece, Contra- And Right-Angle Attachment, Dental
Regulation Name:	Dental handpiece and accessories
Regulatory Class:	Class I
Product Code:	EGS

Predicate devices

The SANAO is substantially equivalent to the following legally marketed devices:

510(k):	K071891
Trade name:	STATIS
	Models 1.5L / 1.1 / 1.1L / 4.1 / 1.1ST / 6.1
Product code:	EFB
Classification Name:	Handpiece, Air-powered, Dental

The STATIS Handpieces Slow-Speed Models STATIS 1.5L / 1.1 / 1.1L / 4.1 / 1.1ST / 6.1 are the exact predicate devices for SANAO Handpieces 200L / 40L / 40 / 40ST/ 10L / 10 / PSI / PSO.

Description of the device

All SANAO Contra-Angle and Straight dental handpieces can be powered by an air-motor or an electronic micro-motor and are intended for use by trained professionals in the field of general dentistry. They are ergonomically shaped, reusable and some models are optionally available with a glass rod lighting system. Depending on the model the devices possess a 1- or 3- port spray or no spray. For different applications and tools there is a range of devices available with different transmissions for maximum output rotations ranging from 8,000 to 200,000 rpm. The devices are color-coded according to their respective gear ratio. The shanks of the instruments are in conformance with the respective ISO standards.

Statement of intended use

The SANAO instruments are intended to be used for general dentistry work. The intended use of the respective instruments is depending on the gear ratio.

- **SANAO 200 L / 40 ST**: The removal of decayed matter, cavity and crown preparations, the removal of fillings and surface finishing of tooth and restoration surfaces.

- **SANAO 40 / 40 L / 10 / 10 L**: Cavity preparations, caries excavation, endodontics, surface finishing of tooth and restoration surfaces.

- **SANAO PSI / PSO**: prophylaxis treatment.

Summary of Technological Characteristics

The devices have been designed according to the following standards:

Performance	ISO -7785-2 Straight and Geared Angle Handpieces
Coupling for instruments	ISO - 1797 Dentistry – Shanks for rotary instruments
Coupling for motor	ISO - 3964 Dental Handpieces Coupling dimensions

For user comfort, the SANAO handpieces are ergonomically shaped. All contact surfaces with the patient are made out of stainless steel. The devices can be powered by an air-motor or an electronic micro-motor. Some models are available with a glass rod lighting system. Depending on the model the devices either possess a 1- or a 3- port spray or no spray. The different transmissions allow for different maximum output rotations ranging from 8,000 to 200,000 rpm.

Clinical and non-clinical tests

A non-clinical evaluation, based on literature research, has been done. The evaluation of the applicable market data showed that SANAO handpieces do not pose more known or new clinical risks than similar medical devices currently on the market. Based on those results clinical test have not been executed.

Statement of substantial equivalence

The SANAO dental handpieces are similar in design, function and intended use to other dental handpieces currently distributed in the U.S. An example for substantially equivalent devices are the STATIS Contra-Angle and Straight Handpieces.

The following tables show a comparison between the different SANAO dental handpieces and the predicates.

Comparison SANAO 200L / STATIS 1.5L

	SANAO 200L	STATIS 1.5L (K071891)
Picture		
Indications for Use	This medical device is: • intended for dental treatments only • suggested for the following applications: The removal of decayed matter, cavity and crown preparations, the removal of fillings and surface finishing of tooth and restoration surfaces.	This medical device is: • intended for dental treatments only • suggested for the following applications: Crown preparation and all other tasks that require the highest level of controlled power
Device Design		

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	SANAO 200L	STATIS 1.5L (K071891)
Design	Contra-Angle	Contra-Angle
Ratio	1:5	1:5
identification	Red	Red
Cooling	Water/Air	Water/Air
Spray	Yes	Yes
Air water ports	3 port	3 port
Operational modes	Powered by air motor or electronic micro-motor	Powered by air motor or electronic micro-motor
Light	Yes	Yes
Fiberoptics	Yes	Yes
Dimensions (mm)	Head Height: 13.9 Head Ø: 10.2 Overall length:97.7	Head Height: 15.2 Head Ø: 9.8 Overall length:95.8
Type of chuck	Push button	Push button
Coupling with motor	ISO 3964	ISO 3964
Coupling instrument	ISO 1797 type 3 (1,60mm)	ISO 1797 type 3 (1,60mm)
Composition of materials		
Patient contact surfaces	Stainless Steel covered with Chrome PEEK	Stainless Steel covered with Chrome
Water Lines	Stainless steel 304L	Stainless steel 304L
Technical specification		
Chuck	Push button	Push button
Light intensity	7,500 LUX	5,000 Lux
Bur Extraction force	> 22N	>22N
Recommended settings - Air cooling	8 Nl/mn at 2.5bar/36.3psi	8-10 Nl/mn
Recommended settings - air/water pressure	Spray air 2.7 bar/39.2 psi Water spray 2 bar/29 psi	Spray air 36 psi Water spray 36 psi

	SANAO 200L	STATIS 1.5L (K071891)
Speed input max.	40,000 rpm	40,000 rpm
Speed output max.	200,000 rpm	200,000 rpm
Chuck design	ISO 1797 type 3 Shaft Ø: 1.6mm Length 25 mm	ISO 1797 type 3 Shaft Ø: 1.6mm Length 21mm

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Comparison SANAO 40L / 40 STATIS vs. 1.1 / 1.1L

	SANAO 40L / 40	STATIS 1.1 / 1.1L (K071891)
Picture		
Indications for Use	This medical device is: • intended for dental treatment only • suggested for the following applications: preparation of cavities, caries excavation, endodontic applications, processing of tooth and restoration surfaces.	This medical device is: • intended for dental treatment only • suggested for the following applications: polishing, preparing, reducing and excavation
Device Design		
Design	Contra-Angle	Contra-Angle
Ratio	40L / 40 1:1	1.1/ 1.1L 1:1
identification	Blue	Blue
Cooling	Water/Air	Water/Air
Spray	Yes	Yes
Air water ports	1 port	3 port
Operational modes	Powered by air motor or electronic micro-motor	Powered by air motor or electronic micro-motor
Light	Yes, for L model	Yes, for L model
Fiberoptics	Yes	Yes
Dimensions (mm)	Head Height: 13.9 Head Ø: 10.2 Overall length:97.7	Head Height: 15.2 Head Ø: 9.8 Overall length:95.8
Type of chuck	Push button	Push button
Coupling with motor	ISO 3964	ISO 3964
Coupling instrument	ISO 1797 type 1 (2,35mm)	ISO 1797 type 1 (2,35mm)
Composition of materials		
Patient contact surfaces	Stainless Steel covered with Chrome PEEK	Stainless Steel covered with Chrome
Water Lines	Stainless steel 304L	Stainless steel 304L
Technical specification		
Chuck	Push button	Push button

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	SANAO 40L / 40	STATIS 1.1 / 1.1L (K071891)
Light intensity	11,300 LUX (for L model)	6,300 Lux (for L model)
Bur Extraction force	> 45 N	>45N
Recommended settings - air cooling	8 Nl/mn at 2.5bar/36.3psi	8-10 Nl/mn
Recommended settings - air/water pressure	Spray air 2.7 bar/39.2 psi Water spray 2 bar/29 psi	Spray air 36 psi Water spray 36 psi
Speed input max.	40,000 rpm	40,000 rpm
Speed output max.	40,000 rpm	40,000 rpm
Chuck design	ISO 1797 type 1 Shaft Ø: 2.334 - 2.350mm Length 22 mm	ISO 1797 type 1 Shaft Ø: 2.350mm Length: Unknown

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Comparison SANAO 10L / 10 vs. STATIS 4.1

	SANAO 10L / 10	STATIS 4.1 (K071891)
Picture		
Indications for Use	This medical device is: • intended for dental treatment only • suggested for the following applications: preparation of cavities, caries excavation, endodontic applications, processing of tooth and restoration surfaces.	This medical device is: • intended for dental treatment only • suggested for the following applications: 4.1: removing caries, endodontics, plaque and polishing of the tooth surface after oral hygiene treatment
Device Design		
Design	Contra-Angle	Contra-Angle
Ratio	5:1	4:1
identification	Green	Green
Cooling	Water/Air	Water/Air
Spray	Yes	Yes
Air water ports	1 port	3 port
Operational modes	Powered by air motor or electronic micro-motor	Powered by air motor or electronic micro-motor
Light	Yes, for L model	No
Fiberoptics	Yes, for L model	No
Dimensions (mm)	Head Height: 13.9 Head Ø: 10.2 Overall length:97.7	Head Height: 15.2 Head Ø: 9.8 Overall length:95.8
Type of chuck	Push button	Push button
Coupling with motor	ISO 3964	ISO 3964
Coupling instrument	ISO 1797 type 1 (2,35mm)	ISO 1797 type 1 (2,35mm)
Composition of materials		

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	SANAO 10L / 10	STATIS 4.1 (K071891)
Patient contact surfaces	Stainless Steel covered with Chrome PEEK	Stainless Steel covered with Chrome
Water Lines	Stainless steel 304L	Stainless steel 304L
Technical specification		
Chuck	Push button	Push button
Light intensity	10,300 LUX (for L model)	Not applicable
Bur Extraction force	> 45N	> 45N
Recommended settings - air cooling	8 Nl/mn at 2.5bar/36.3psi	8-10 Nl/mn
Recommended settings - air/water pressure	Spray air 2.7 bar/39.2 psi Water spray 2 bar/29 psi	Spray air 36 psi Water spray 36 psi
Speed input max.	40,000 rpm	40,000 rpm
Speed output max.	8,000 rpm	10,000 rpm
Chuck design	ISO 1797 type 1 Shaft Ø: 2.334 - 2.350 mm Length 25 mm	ISO 1797 type 1 Shaft Ø: 2.350 mm Length: unknown

Comparison SANAO 40 STvs. STATIS 1.1 ST

	SANAO 40 ST	STATIS 1.1 ST (K071891)
Picture		
Indications for Use	This medical device is: • only intended for dental treatment. • suggested for the following applications: Removal of carious material, cavities and crown preparations, removal of fillings, processing of tooth and restoration surfaces.	This medical device is: • only intended for dental treatment. • suggested for the following applications: Preparation in the anterior region, osteotomy, root resection or extra-oral prosthesis correction.
Device Design		
Design	Straight handpiece	Straight handpiece
Ratio	1:1	1:1
identification	Blue	Blue
Cooling	Water/Air	Water/Air
Spray	Yes	Yes
Air water ports	1 port	1 port
Operational modes	Powered by air motor or electronic micro-motor	Powered by air motor or electronic micro-motor
Light	No	No
Fiberoptics	No	No
Dimensions (mm)	Ø: 19.9 Overall length:83.7	Ø: 19.6 Overall length:84.9
Type of chuck	Mechanical chuck	Mechanical chuck

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	SANAO 40 ST	STATIS 1.1 ST (K071891)
Coupling with motor	ISO 3964	ISO 3964
Coupling instrument	ISO 1797 type 2 (2,35mm)	ISO 1797 type 2 (2,35mm)
Composition of materials		
Patient contact surfaces	Stainless Steel covered with Chrome	Stainless Steel covered with Chrome
Water Lines	Stainless steel 304L	Stainless steel 304L
Technical specification		
Chuck	Mechanical chuck	Mechanical chuck
Light intensity	Not applicable	Not applicable
Bur Extraction force	> 45N	>45N
Recommended settings - air cooling	8 Nl/mn at 2.5bar/36.3psi	8-10 Nl/mn
Recommended settings - air/water pressure	Spray air 2.7 bar/39.2 psi Water spray 2 bar/29 psi	Spray air 36 psi Water spray 36 psi
Speed input max.	40,000 rpm	40,000 rpm
Speed output max.	40,000 rpm	40,000 rpm
Chuck design	ISO 1797 type 2 Shaft Ø: 2.334 - 2.350 mm Length 25 mm	ISO 1797 type 2 Shaft Ø: 2.350 Length: unknown

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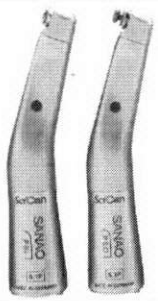
Comparison SANAO PSI / PSO vs. STATIS 6.1

	SANAO PSI / PSO	STATIS 6.1 (K071891)
Picture		
Indications for Use	This medical device is: • only intended for dental treatment. • suggested for the following application: prophylaxis treatment	This medical device is: • only intended for dental treatment. • suggested for the following applications: prophylaxis
Device Design		
Design	Contra-Angle	Contra-Angle
Ratio	5:1	6:1
identification	Green	Green
Cooling	Not applicable	Not applicable
Spray	No	No
Air water ports	None	None
Operational modes	Powered by air motor or electronic micro-motor	Powered by air motor or electronic micro-motor
Light	No light	No light
Fiberoptics	None	None
Dimensions (mm)	Head Height: PSI 10.8mm PSO 13.8mm Head Ø: 8.2 Overall length:96.7	Head Height: 15.2 Head Ø: 7.3 Overall length:88.7
Type of chuck	Not applicable	Not applicable
Coupling with motor	ISO 3964	ISO 3964
Coupling instrument	PSI with Screw-In-Function (with ISO 13295 type 3) PSO with mandrels with Snap-On-	For mandrels with Snap-On-Function (ISO 13295 type 5) or mandrels with Screw-In function (ISO 13295 type 3)

	SANAO PSI / PSO	STATIS 6.1 (K071891)
	Function (ISO 13295 type 5)	
Composition of materials		
Patient contact surfaces	Stainless Steel covered with Chrome PEEK	Stainless Steel covered with Chrome
Water Lines	No water line	No water line
Technical specification		
Chuck	No chuck	No chuck
Light intensity	Not applicable	Not applicable
Bur Extraction force	Not applicable	Not applicable
Recommended settings - air cooling	Not applicable	Not applicable
Recommended settings - air/water pressure	Not applicable	Not applicable
Speed input max.	40,000 rpm	40,000 rpm
Speed output max.	8,000 rpm	6,666 rpm
Chuck design	No chuck	No chuck

As shown in the comparison tables, the indications for use of the SANAO dental handpieces are substantially equivalent to those of the SciCan STATIS Handpieces (K071891). As described above, the principle of operation and design features of the SANAO Handpieces are identical to those of the predicates. The gear ratio of SANAO PSI / PSO / 10 / 10L is different to that of the predicates. Therefore, the maximum rotation speed at the chuck is different between the SANAO PSI / PSO / 10 / 10L and the predicates. Also some differences can be found in the light intensity, dimensions and the external material from SANAO to STATIS. In order to evaluate that those differences do not affect safety and effectiveness of the SANAO Handpieces bench testing was performed. Bench testing demonstrated that the SANAO Handpieces met the requirement of the ISO 7785-2 which was used for evaluation of the predicate devices. Based on the above results, the SANAO Handpieces are substantially equivalent to the predicates and do not raise any new safety and effectiveness concern.

Bench Testing

The Bench tests were performed in order to ensure the safety and effectiveness of the SANAO Handpieces, verify conformity to ISO 7785-2 and demonstrate substantial equivalence to the predicates. All samples were compliant with ISO 7785-2 and demonstrated substantial equivalance to the predicates.

Risk analysis method & actions

A Risk Management Plan to identify the risks and activities for managing those risks was carried out during design and development of the SANAO Dental handpieces, accessories and associated devices.

The Risk Analysis of the SANAO line of dental handpieces was conducted in accordance with ISO 14971: 2007. The analysis showed that the level of risk associated with the SANAO handpieces is minor and not any greater as the level of risks identified for similar medical devices currently on the market.

Applicable Standards

	Standards No.	Standards Organization	Standards Title	Version
1	ISO 10993-1	ISO	Biological evaluation of medical devices	2009
2	ISO 14971	ISO	Medical devices – Application of risk management to medical devices	2007
3	ISO 7785-2	ISO	Dental Handpieces – Part 2 Straight and Geared Angled Handpieces	1995
4	ISO 17664	ISO	Sterilization of medical devices – Information to be provided by the manufacturer for the processing of resterilizable medical devices	2004
5	ISO 17665-1	ISO	Sterilization of health care products – Moist heat – Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices	2006
6	ISO 9687	ISO	Dental equipment – Graphical symbols	1995
7	ISO 21531	ISO	Dentistry – Graphical symbols for dental instruments	2009
8	ISO 3964	ISO	Dental Handpieces – Coupling Dimensions	1982
9	ISO 1797-1	ISO	Dental Rotary Instruments - Shanks	2011

Conclusion

The Indications for Use of the SANAO Handpieces are substantially equivalent to those of the SciCan STATIS (K071891). In addition, the principle of operation and design features of the SANAO Handpieces are identical to those of the predicates. The gear ratio of the SANAO PSI / PSO / 10 / 10L is different to that of the predicates. Therefore, the maximum rotation speed at the chuck is different between the SANAO PSI / PSO / 10 / 10L and the predicates. There are also some

differences in the light intensity, dimensions and the external material from SANAO to the predicates. Although there are those differences in characteristics between the SANAO Handpieces and the predicates, a number of performance testing indicated that the SANAO Handpieces met the requirements of the recognized consensus or voluntary standard. Based on the above results, we conclude that the SANAO-Handpieces are substantially equivalent to the predicates and do not raise any new safety and effectiveness concern.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

January 31,2014

SciCan GmbH
C/O Mr. Alexander Schapovalov
TUV SUD American, Incorporated
1775 Old Highway 8 NW, Suite 104
New Brighton, MN 56112-1891

Re: K132356
Trade/Device Name: SANAO Dental Handpieces
Regulation Number: 21 CFR 872.4200
Regulation Name: Dental Handpiece and Accessories
Regulatory Class: I
Product Code: EGS
Dated: January 12, 2014
Received: January 16, 2014

Dear Mr. Schapovalov:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kwame O. Ulmer -S for

Erin I. Keith, M.S.
Acting Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

001_INDICATION FOR USE STATEMENT

510(k) Number (if known): K 132356

Device Name: SANAO Dental Handpieces

Indications for Use

This medical device is only intended for dental treatment in the area of dentistry. Is is intended to be used for the following applications:

- **SANAO 200 L / 40 ST**: The removal of decayed matter, cavity and crown preparations, the removal of fillings and surface finishing of tooth and restoration surfaces.
- **SANAO 40 / 40 L / 10 / 10 L**: Cavity preparations, caries excavation, endodontics, surface finishing of tooth and restoration surfaces.
- **SANAO PSI / PSO**: prophylaxis treatment.

Prescription Use __X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mary S. Runner -S
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